

09-15-04

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Express Mail Label No. \_\_\_\_\_ Dated: \_\_\_\_\_

Docket No.: 01946/100B861-US2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Andrea Leone-Bay, et al.

Application No.: 10/005,511

Confirmation No.: 2401

Filed: November 7, 2001

Art Unit: 1615

For: COMPOUNDS AND COMPOSITIONS FOR  
DELIVERING ACTIVE AGENTS

Examiner: J. M. Spear

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

09/16/2004 FFANAI2 00000056 10005511

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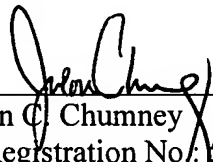
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: September 14, 2004

Respectfully submitted,

By   
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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE

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Sheet 1 of 2.

Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				Application Number	10/005,511
				Filing Date	November 7, 2001
				First Named Inventor	Andrea Leone-Bay
				Art Unit	1615
				Examiner Name	James Spear
Sheet	1	of	2	Attorney Docket Number	01946/100B861 -US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Memorandum
	1	5,935,601	8/10/1999	Leone-Bay, et al.	
	2	5,955,503	9/21/1999	Leone-Bay, et al.	
	3	5,962,710	10/5/1999	Gschneider, et al.	
	4	5,965,121	10/12/1999	Leone-Bay, et al.	
	5	6,084,112	7/4/2000	Ho, et al.	
	6	6,100,298	8/8/2000	Leone-Bay, et al.	
	7	6,180,140	1/30/2001	Leone-Bay, et al.	
	8	6,344,213	2/5/2002	Leone-Bay, et al.	
	9	6,346,242	2/12/2002	Leone-Bay, et al.	Certificate of Correction
	10	6,348,207	2/19/2002	Milstein, et al.	Certificate of Correction
	11	6,358,504	3/19/2002	Leone-Bay, et al.	
	12	6,384,278	5/7/2002	Tang, et al.	
	13	6,391,303	5/21/2002	Haas, et al.	
	14	6,399,798	6/4/2002	Gschneider, et al.	
	15	6,428,780	8/6/2002	Leone-Bay, et al.	
	16	6,440,929	8/27/2002	Milstein, et al.	
	17	6,461,643	10/8/2002	Milstein, et al.	
	18	6,525,020	2/25/2003	Leone-Bay, et al.	
	19	US 2002-0001591	1/3/2002	Santiago, et al.	
	20	6,610,329	8/26/2003	Santiago, et al.	
	21	6,623,731	9/23/2003	Leone-Bay, et al.	
	22	6,627,228	9/30/2003	Milstein, et al.	
	23	6,642,411	11/4/2003	Leone-Bay, et al.	
	24	6,646,162	11/11/2003	Tang, et al.	
	25	US 2002-0120009	8/29/2002	Leone-Bay, et al.	
	26	6,663,887	12/16/2003	Leone-Bay, et al.	
	27	6,693,073	2/17/2004	Milstein, et al.	
	28	6,693,208	2/17/2004	Gschneider, et al.	
	29	6,699,467	3/2/2004	Leone-Bay, et al.	
	30	5,693,338	12/02/1997	Milstein, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	31	W095/28920	11/02/1995	Emisphere Technologies, Inc.		
	32	W095/28838	11/02/1995	Emisphere Technologies, Inc.		
	33	W096/12473	5/2/1996	Emisphere Technologies, Inc.		
	34	W096/12474	5/2/1996	Emisphere Technologies, Inc.		
	35	W096/12475	5/2/1996	Emisphere Technologies, Inc.		
	36	W096/21464	7/18/1996	Emisphere Technologies, Inc.		
{W:10194611 00b861us2}				DATE CONSIDERED:		



PTO/SB/08A (10-01)

Approved for use through 10/31/2002.OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Sheet 2 of 2.

<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/005,511
				Filing Date	November 7, 2001
				First Named Inventor	Andrea Leone-Bay
				Art Unit	1615
				Examiner Name	James Spear
Sheet	2	of	2	Attorney Docket Number	01946/100B861 -US2

37	WO97/10197	3/20/1997	Emisphere Technologies, Inc.	
38	WO97/36480	10/9/1997	Emisphere Technologies, Inc.	
39	WO98/21951	5/28/1998	Emisphere Technologies, Inc.	
40	WO98/25589	6/18/1998	Emisphere Technologies, Inc.	
41	WO98/34632	8/13/1998	Emisphere Technologies, Inc.	
42	WO98/50341	11/12/1998	Emisphere Technologies, Inc.	
43	WO99/16427	4/8/1999	Emisphere Technologies, Inc.	
44	WO00/40203	7/13/2000	Emisphere Technologies, Inc. And Virginia Commonwealth University	
45	WO00/46182	8/10/2000	Emisphere Technologies, Inc.	
46	WO00/50386	8/31/2000	Emisphere Technologies, Inc.	
47	WO00/59480	10/12/2000	Emisphere Technologies, Inc.	
48	WO00/59863	10/12/2000	Emisphere Technologies, Inc.	
49	WO01/32130	5/10/2001	Emisphere Technologies, Inc.	
50	WO01/32596	5/10/2001	Emisphere Technologies, Inc.	
51	WO01/44199	6/21/2001	Emisphere Technologies, Inc.	
52	WO01/51454	7/19/2001	Emisphere Technologies, Inc.	
53	WO01/70219	9/27/2001	Emisphere Technologies, Inc.	
54	WO01/92206	12/6/2001	Emisphere Technologies, Inc.	
55	WO02/069937	9/12/2002	Emisphere Technologies, Inc.	
56	WO02/070438	9/12/2002	Emisphere Technologies, Inc.	
57	WO02/100338	12/19/2002	Emisphere Technologies, Inc.	
58	WO02/19969	3/14/2002	Emisphere Technologies, Inc.	
59	WO03/026582	4/3/2003	Emisphere Technologies, Inc.	
60	WO03/045306	6/5/2003	Emisphere Technologies, Inc.	
61	WO03/057170	7/17/2003	Emisphere Technologies, Inc.	
62	WO03/057650	7/17/2003	Emisphere Technologies, Inc.	
63	FR985.340	11/2/1966	Francia Farmaceutica	
64	WO99/29705	6/17/1999	Glycomed Inc.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	65	HO KOC-KAN; et al. "Solution Phase Preparation of Highly Pure Amide Mixtures Via In-Situ Chlorotrimethylsilane Protection and Activation" Synthetic Communication, vol. 27, no. 5: 883-895 (1997)	
	66	LEONE-BAY, A. "Synthesis And Evaluation Of Compounds That Facilitate The Gastrointestinal Absorption Of Heparin"; Journal of Medicinal Chemistry vol 41, 1163-1171 (1998)	
	67	Francia Farmaceutica "γ-(o-Hydroxybenzamido)-Butyric Acid" Chem Abstracts Vol. 10 114838e (1969)	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

{W:101946\1 00b861us2}	DATE CONSIDERED:
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Application No. (if known): 10/005,511

Attorney Docket No.: 01946/100B861-US2

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV 367696285-US in an envelope addressed to:

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on September 14, 2004  
Date

*D. Davis*  
Signature  
*D. Davis*

Typed or printed name of person signing Certificate

Note: Information Disclosure Statement (2 pages)  
List of References (PTO\SB\08a\b form) (2 pages);  
67 References/Publications;  
Fee Transmittal for FY 2004 (1 page);  
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PTO/SB/17 (10-03)  
Approved for use through 7/31/2006. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

## Complete if Known

Application Number	10/005,511
Filing Date	November 7, 2001
First Named Inventor	Andrea Leone-Bay
Examiner Name	J. M. Spear
Art Unit	1615
Attorney Docket No.	01946/100B861-US2

## METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account

Deposit Account Number

04-0100

Deposit Account Name

Darby & Darby P.C.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$) 0.00

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
	** =	x	= 0.00
Independent Claims	** =	x	= 0.00
Multiple Dependent			=

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0.00

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
Other fee (specify)				Information Disclosure Statement	180.00

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 180.00

## SUBMITTED BY

Name (Print/Type) Jason C. Chumney

Registration No. (Attorney/Agent)

54,781

(Complete if applicable)

Telephone (212) 527-7765

Signature

Date

September 14, 2004

Express Mail Label No.

Dated: \_\_\_\_\_

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